PB91-187062

Pesticide Fact Sheet No. 222: Fenamiphos

(U.S.) Environmental Protection Agency, Washington, DC

Jun 87

U.S. Department of Commerce
National Technical Information Service
NTIS

PB91-187062

REPORT DOCUMENTATION PAGE

1. REPORT NO.

2.

4. Title and Subtitle

EPA Pesticide Fact Sheets - Fenamiphos No. 222

5. Report Date
June 1987

6.

7. Author(s)
EPA, Office of Pesticide Programs, Registration Division

8. Performing Organization Rept. No.
540/FS-91-133

9. Performing Organization Name and Address
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (H7505C)
401 M Street, SW
Washington, D.C. 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.
(C)
(G)

12. Sponsoring Organization Name and Address

Same as #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement:

Publicly Available

19. Security Class (This Report)
Unclassified

21. No. of Pages

20. Security Class (This Page)
Unclassified

22. Price

(See ANSI-Z39.18) See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

REPRODUCED BY
U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL
INFORMATION SERVICE
SPRINGFIELD, VA 22161

United States
Environmental Protection
Agency

Office of Pesticides
and Toxic Substances
(H7501C)

540/FS-91-133

PB91-187062

EPA

Pesticide Fact Sheet

Name of Chemical: Fenamiphos

Reason for Issuance: Registration Standard

Date Issued: June 1987

Fact Sheet Number: 222

1. DESCRIPTION OF CHEMICAL

Common Name: Fenamiphos

Chemical Name: O-ethyl-O-(3-methyl-4-methyl-thiophenyl)-isopropylphosphoramidate

CAS Number: 22224-92-6

OPP (Shaughnessy) Number: 100601

Trade Names: Nemacur 15G, Nemacur 3

Registrant: Mobay Chemical Co.

2. USE PATTERNS AND FORMULATIONS

Type of Pesticide: Systemic Nematicide/Insecticide

Pests Controlled: Nematodes, Thrips

Predominant Uses: field and vegetable crops, orchards, vineyards, non-bearing orchards, nursery stock, ornamentals

Formulation Types: emulsifiable concentrate and granular

Method of Application: soil treatment by ground spray equipment, by granular application equipment, or by incorporation into irrigation water. Soil incorporation or irrigation immediately after treatment is required. All formulations are being restricted through this registration standard. Applicators must be certified or under direct supervision of a certified applicator.

7 pages

3. SCIENCE FINDINGS

Toxicology Characteristics:

Acute Oral Toxicity (rat)	LD_{50} 2.7 mg/kg (category I)
Acute Dermal Toxicity (rabbit)	LD_{50} 178.8 mg/kg (category I)
Acute Inhalation Toxicity (rat)	LC_{50} 0.1 mg/L (category I)
Primary Dermal Irritation (rabbit)	non-irritating (category IV)
Primary Eye Irritation (rabbit)	slightly irritating (category III)
Dermal Sensitization (guinea pig)	not a sensitizer
Delayed Neurotoxicity (hen)	not a delayed neurotoxicant

Subchronic Effects

90-day Feeding (rat)	NOEL for cholinesterase inhibition 4 ppm
90-day Feeding (dog)	NOEL for cholinesterase inhibition 1 ppm
21-day Dermal (rabbit)	NOEL 0.5 mg/kg/day

Chronic Effects

2-year chronic feeding/ oncogenicity (rats):	No dose related increase in neoplastic and non-neoplastic lesions was observed. Dietary cholinesterase NOEL is 1.0 ppm. Systemic NOEL is 10 ppm.
2-year chronic feeding (dogs):	No gross or histopathological changes were attributed to dietary levels of fenamiphos. Dietary cholinesterase NOEL is 1.0 ppm. Systemic NOEL is 10 ppm.

Chronic Effects (continued)

18-month oncogenicity (mice):	Fenamiphos was not shown to be oncogenic in mice.
Multigeneration reproduction (rats):	No adverse reproductive effects were observed.
Mutagenicity - gene mutation:	Negative.
Chromosomal aberration:	Negative.

Physiological and biochemical behavioral characteristics

Mechanism of pesticidal action:	Organophosphate/ cholinesterase inhibitor

Metabolism in plants and animals: The nature of the residue in plants is adequately understood. The nature of the residue in animals is not adequately understood. Tolerances for residues of fenamiphos in food items derived from plants are currently expressed in terms of the combined residues of fenamiphos and its cholinesterase-inhibiting metabolites, fenamiphos sulfoxide and fenamiphos sulfone. Tolerances for residues of fenamiphos in food items derived from animals are expressed in terms of the combined residues of fenamiphos and its sulfoxide and sulfone as well as des-isopropyl fenamiphos, des-isopropyl fenamiphos sulfoxide and des-isopropyl fenamiphos sulfone.

Environmental Characteristics: Available data are insufficient to fully assess the environmental fate and transport and potential exposure to fenamiphos. Except for the two studies listed below, all the available environmental fate data do not meet the guideline standards for acceptable testing.

Hydrolysis: Fenamiphos is relatively stable in neutral and alkaline solutions.

Photodegradation in Water: Fenamiphos degrades with a half life of 2 to 4 hours in ph 7 buffered water irradiated with artificial light.

Groundwater: The potential for fenamiphos to reach ground water cannot be determined at this time. Some existing studies, though deficient in some respects, show it does leach to some degree. The Agency will evaluate the

potential of fenamiphos to contaminate ground water after it has received and evaluated the following required data: photodegradation in air, aerobic and anaerobic metabolism, mobility, and field dissipation. The sulfoxide and sulfone metabolites of fenamiphos are included in the National Survey for Pesticides in Drinking Water, in lieu of parent fenamiphos, as the parent readily degrades.

Ecological Characteristics:

Avian acute oral toxicity:	LD_{50} 1.6 mg/kg
Avian dietary toxicity:	LC_{50} 38 ppm
Avian reproduction:	
bobwhite quail	NOEL 2 ppm
mallard duck	NOEL 8 ppm
Field studies:	Studies using both the granular and emulsifiable concentrate formulations have shown some avian and mammalian mortality.
Fish acute toxicity:	LC_{50} 9.6 ppb

Tolerance Reassessment:

Tolerances have been established for residues of fenamiphos in a variety of raw agricultural commodities, in meat, fat and meat byproducts (40 CFR 180.349 [a] and [b]), and in processed food (21 CFR 193.463) and feed (21 CFR 561.232).

Available toxicology and residue chemistry data are insufficient to permit the Agency to conduct a full tolerance reassessment. A provisional acceptable daily intake (PADI) has been set at 0.00025 mg/kg/day, based on the NOEL from a 2-year dog feeding study of 0.025 mg/kg/day (1 ppm) for cholinesterase inhibition and an uncertainty factor of 100 to account for the lack of an acceptable teratology study. The Theoretical Maximum Residue Contribution (TMRC) for the U.S. population average based on anticipated residues and percent crop treated, is 0.00011 mg/kg/day which corresponds to 42% of the PADI. It is possible that resolution of the teratology data gap will allow for a lower uncertainty factor which will result in a higher ADI and consequently a lower percentage of the ADI occupied by the TMRC.

4. SUMMARY OF REGULATORY POSITION AND RATIONALE

1. The Agency will not, at this time, initiate a Special Review [40 CFR Part 154] of fenamiphos. After review and evaluation of the required studies for fish and wildlife the Agency will reconsider the possibility of a Special Review. Acceptable protocols for conducting the avian, mammalian, and fish field studies must be submitted within six months of the issuance of the standard and be accepted by the Agency before the initiation of field work. Annual progress reports must also be submitted for the duration of the study. The application rates used in these studies must be the lowest possible rates that are still efficacious as indicated by the required efficacy data (refer to Regulatory Position 3).

Rationale: Fenamiphos is very highly toxic to birds (LD_{50} 1.6 mg/kg) and mammals (LD_{50} 2.7 mg/kg) as well as to cold (LC_{50} 72.1 ppb) and warm water (LC_{50} 9.6 ppb) fish species.

Estimated environmental concentrations (EECs) of the granular formulation of fenamiphos exceed the acute oral LD_{50} for the most sensitive avian species tested, the bobwhite quail, and the estimated LD_{50} values for 5 other avian species. EECs also exceed the LD_{50} for the rat and the estimated LD_{50} values for two other mammalian species. EECs of the emulsifiable concentrate formulation indicate that fenamiphos residues exceed the calculated subacute dietary LC_{50} for four avian species.

Field studies using both granular and spray formulations of fenamiphos according to label directions have shown some avian and mammalian mortality. These studies also suggest that soil incorporation and/or irrigation immediately following application reduces hazards. However, because of design deficiencies these studies do not meet guideline requirements; therefore, a terrestrial field study is being required to determine if the hazards indicated by lab and field studies are below levels of concern for mammalian and avian species under actual use conditions.

Estimated environmental concentrations for water contaminated by aerial application to crops and for runoff exceed the LC_{50} values for bluegill sunfish, and therefore, would cause significant adverse effects. Thus, the following tests are being required to fully assess the potential exposure and toxicity of fenamiphos to aquatic environments: freshwater fish toxicity (on EPs), freshwater invertebrate acute toxicity (using the technical and EPs), estuarine and marine acute toxicity, fish early life stage testing, fish life cycle, aquatic invertebrate life cycle, aquatic organism accumulation, and simulated and actual field testing of aquatic organisms.

2. The Agency is requiring restricted use classification for all fenamiphos formulated products.

Rationale: Fenamiphos exceeds the restricted use criteria set forth in 40 CFR 162.11(c)(2)(ii) and (iii). Use of fenamiphos formulations has resulted in mortality to birds and mammals. Fenamiphos is acutely toxic to laboratory animals, Toxicity Category I, by the oral, dermal, and inhalation routes of exposure. It is also very highly toxic to birds as well as cold and warm water fish species. Use of fenamiphos exceeds the restricted use criteria for fish and wildlife; calculated residues exceed 1/5 the acute oral LD_{50} for mammals, 1/5 the subacute dietary LC_{50} for avian species, and 1/10 the acute LC_{50} for aquatic organisms. In addition, use of fenamiphos has resulted in mortality to birds and mammals. Accordingly, the Agency has determined that the risks to humans, fish, and wildlife, associated with the unrestricted use of fenamiphos products, constitute unreasonable adverse effects. Restricting the use of all fenamiphos products will reduce exposure and the potential for acute toxicity. Field studies on birds, mammals, and aquatic organisms, are being required to determine actual exposure levels and potential hazard.

3. The Agency is requiring that efficacy data be submitted to support all currently registered application rates.

Rationale: EECs based on the maximum application rate exceed LD_{50} values for birds and mammals and the LC_{50} value for fish. Therefore, the Agency is requiring that efficacy data be submitted within six months of the issuance of the standard to support the current application rates. If such data indicate that rates could be lowered with minimal decrease in efficacy the Agency will require that all labels be revised to the lowest possible rates that are still efficacious. These labeling changes would reduce environmental concentrations of the pesticide while substantive data on the effects on fish and wildlife are being collected.

4. The Agency is requiring that all labels be revised as follows:

1). Directions for broadcast spray will be deleted for sites which currently have directions for both band and broadcast spray.
2). All labels will prohibit the use of mist sprayers and will direct applicators to use only coarse sprays directed at the soil to reduce the possibility of spray drift.
3). All labels will specifically prohibit aerial application.

Rationale; As stated above, EECs based on the maximum application rate exceed LD_{50} values for mammalian and avian species and the LC_{50} value for aquatic organisms. The above labeling changes would reduce environmental concentrations of the pesticide while substantive data on the effects of fenamiphos on fish and wildlife are being collected.

5. The Agency is requiring endangered species labeling on fenamiphos EPs registered for use on cotton and soybeans in accordance with Pesticide Registration (PR) Notice 87-5 (issued May 1, 1987).

Rationale: Fenamiphos was reviewed for endangered species implications. In order to protect endangered species from harm, endangered species labeling is required.

Use restrictions: All formulations are classified as restricted use pesticides.

Unique label statements:

- Restricted use
- 48-hour reentry interval
- Protective clothing
- Aerial application prohibition
- Endangered species

5. SUMMARY OF MAJOR DATA GAPS

Product Chemistry: All

Residue Chemistry:
- Animal Metabolism
- Residue Analytical Methods (plants and animals)
- Storage Stability Data
- Residue Studies

Environmental Fate:
- Photodegradation (soil)
- Aerobic and Anaerobic Soil Metabolism
- Leaching and Adsorption/Desorption
- Volatility (lab)
- Soil Dissipation
- Rotational Crops (confined and field)
- Fish Accumulation
- Spray Drift Droplet Spectrum and Field Evaluation
- Reentry

Toxicology:
- 21-Day Inhalation (rat)
- Teratology (rat and rabbit)
- Mutagenicity
- Metabolism

Ecological Effects:
- Simulated and Actual Field Testing (birds and mammals)
- Freshwater Fish Toxicity
- Freshwater Invertebrate Acute Toxicity
- Acute Toxicity to Estuarine and Marine Organisms
- Fish Early Life Stage
- Aquatic Invertebrate Life Cycle
- Fish Life Cycle
- Aquatic Organism Accumulation
- Simulated and Actual Field Testing Aquatic Organisms

6. CONTACT PERSON AT EPA

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